DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 18, 2014

MedShape, Incorporated
Mr. Jeremy Blair
Project Manager
1575 Northside Drive, Suite 440
Atlanta, Georgia 30318

Re: K141420
Trade/Device Name: FastForward
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN
Dated: November 14, 2014
Received: November 17, 2014

Dear Mr. Blair:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K141420

Device Name: FastForward

Indications for Use:

The FastForward device is intended to assist in the correction of Hallux Valgus deformities by providing reduction of the 1st Intermetatarsal angle.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

510(k) Number: __K141420__

Date Prepared: November 10, 2014

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

A. Submitter:

MedShape, Inc.
1575 Northside Drive, Suite 440
Atlanta, Georgia 30318

B. Company Contact:

Jeremy Blair
Project Manager
(678) 235-3319(direct)
(404) 249-9158 (fax)
Jeremy.Blair@MedShape.com

C. Device Information:

Trade Name: Fast*Forward*
Common Name: Button

D. Classification Name: *Washer, Bolt Nut*
HTN: Single/multiple component metallic bone fixation appliances and accessories
21 CFR 888.3030

E. Predicate Device(s):

Arthrex Mini Tightrope, K061925

F. Physical Description:

The Fast*Forward* device, consisting of Titanium (Ti-6AL-4V ELI), is a button designed to be implanted on the lateral aspect of the 2nd metatarsal with suture or suture tape.

G. Indications for Use:

The FastForward device is intended to assist in the correction of Hallux Valgus deformities by providing reduction of the 1st Intermetatarsal angle.

H. Comparison of Technological Characteristics:

The FastForward is substantially equivalent in design, function and intended use to the following predicate device:

Arthrex Mini Tightrope, K061925

Any differences between the proposed and predicate devices do not raise safety or efficacy concerns. Pullout/fracture strength testing of the predicate and proposed devices was conducted. The proposed device was evaluated in conjunction with various suture sizes and materials. Monotonic and cyclic tension and shear testing was completed on full constructs which included 1st metatarsal fixation. Testing and analysis substantiates the statement that the proposed device performs equivalently to the predicate device.

MEDSHAPE
1575 Northside Drive, Suite 440
Atlanta, GA 30318
404-249-9156 phone
404-249-9158 fax